

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)	
FENFLURAMINE/DEXFENFLURAMINE))	MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)	
_____)	
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS)	2:16 MD 1203
CORPORATION)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9500

Bartle, J.

June 8, 2018

Miguel A. Larrieu ("Mr. Larrieu" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD").

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, the claimant's attorney must complete Part III if the claimant is represented.

In June 2015, Mr. Larrieu submitted a completed Green Form to the Trust signed by his attesting physician, Marta C. Sayers, M.D., F.A.C.C. Based on an echocardiogram dated March 5, 2015,³ Dr. Sayers attested in Part II of Mr. Larrieu's

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See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Because claimant's March 5, 2015 echocardiogram was performed after the end of the Screening Period, claimant relied on an echocardiogram dated December 9, 2002 to establish his eligibility to receive Matrix Benefits. The Screening Period ended on January 3, 2003 for echocardiograms performed outside of the Trust's Screening Program and on July 3, 2003 for

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Green Form that claimant suffered from severe mitral regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$823,285.⁵

Dr. Sayers also attested that Mr. Larrieu did not suffer from mitral annular calcification. Significantly, the Settlement Agreement requires the reduced payment of Matrix Benefits for a claim based on damage to the mitral valve when mitral annular calcification is present. See id. § IV.B.2.d.(2)(c)ii)d).

The Trust does not contest claimant's entitlement to Level III benefits. Thus the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In October 2015, the Trust forwarded the claim to M. Michele Penkala, M.D., one of its auditing cardiologists, for

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echocardiograms performed in the Trust's Screening Program.
See Settlement Agreement § I.49.

4. Dr. Sayers also attested that claimant suffered from moderate aortic regurgitation and an ejection fraction of less than 30%. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he suffered from "left sided valvular heart disease requiring . . . [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See id. § IV.B.2.c.(3)(a).

review. In audit, Dr. Penkala concluded that there was no reasonable medical basis for finding that claimant did not have mitral annular calcification. In particular, Dr. Penkala stated, "From my review of all the studies (12/9/2002, 4/14/12 and 3/5/15) I did think that significant [mitral annular calcification] was present. In addition, the surgeon noted in his [operative] report: 'evidence that the [mitral valve] had severe calcification of the posterior leaflet, as well as the annulus.'"⁶

Based on Dr. Penkala's findings, the Trust issued a post-audit determination that Mr. Larrieu was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Larrieu contested this adverse determination.⁷ He argued that there was

6. Dr. Penkala also determined that there was no reasonable medical basis for finding that Mr. Larrieu had at least moderate mitral regurgitation between the commencement of Diet Drug use and the end of the Screening Period. This finding would also require the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(a). Given our disposition with respect to the presence of mitral annular calcification, we need not address this issue.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Larrieu's claim.

a reasonable basis for finding that he did not have mitral annular calcification on the December 9, 2002 and March 5, 2015 echocardiograms. In support, Mr. Larrieu submitted a letter from Dr. Sayers that stated that "there is no evidence of mitral annular calcification" and that "[n]o [mitral] annular calcification was mentioned on the [echocardiogram] from 2015 also indicating there would be no [mitral] annular calcification on the [echocardiogram] done in 2002." He also submitted a letter from Kaye M. Bass, B.S., R.D.C.S., R.V.T., which did not address the issue of mitral annular calcification. He noted that two of his echocardiograms have been reviewed by auditing cardiologists who did not find the presence of any mitral annular calcification. Finally, Mr. Larrieu asserted that any mitral annular calcification, if present, was either due to his advanced age or was a relatively minute or insignificant quantity.

Although not required to do so, the Trust forwarded the claim to the auditing cardiologist for a second review. Dr. Penkala submitted a declaration in which she again concluded that there was no reasonable medical basis for finding that Mr. Larrieu did not have mitral annular calcification. Specifically, Dr. Penkala stated:

14. As I noted at audit, the [echocardiogram] study dated 12/9/02 is a

very technically difficult study which had limited images and limited number of views.

15. The 12/9/02 study was apparently performed as a part of a diet drug valve assessment rather than one performed based upon clinical necessity.

16. I agree that no clear [mitral annular calcification] is visible in the parasternal long or short axis views of the 12/9/02 study. However, in the apical 4 chamber and apical 2 chamber view there is a strong suggestion of [mitral annular calcification] especially on the part of the tape, approximately from 11:24:34-11:24:42. It should be noted that the timer is difficult to see clearly. The suggestion of calcification in the annulus is most prominent in the intervalvular area between the mitral and the aortic valves.

17. I also reviewed again the study dated 4/14/12. On this study, the presence of [mitral annular calcification] was most evident in loops 1, 9, 25 and 26. Again, the calcification is most notable in the intervalvular area between the mitral and aortic valves.

18. Further, I reviewed again the Echocardiogram of Attestation identified in the Green Form, the [transesophageal echocardiogram] dated 3/5/15. On review of this study, [mitral annular calcification] is seen in images (runs) 12, 15, 16 and 41. Although the report of this study is silent as to the presence or absence of mitral annular calcification, [mitral annular calcification] is seen on the study.

19. There is no reasonable medical basis for concluding that Mr. Larrieu did not have [mitral annular calcification].

20. There is no reasonable medical basis to conclude that the presence

of [mitral annular calcification] was minute or of insignificant quantity or degree to register on the 2015 [transesophageal echocardiogram], as suggested by Claimant's attorney, Mr. Coates. Indeed, review of the operative report paints a different picture: "The mitral valve was exposed and inspected. It was immediately evident that the mitral valve had severe calcification of the posterior mitral valve leaflet as well as the annulus mainly as the level of P1 and P2." Later in the report the surgeon notes (in reference to the MITRAL valve): "As I mentioned before the valve was very calcified including the annulus. Therefore I decided to replace the valve."

See Operative Report.

Thereafter the Trust issued a final post-audit determination again in which it concluded that Mr. Larrieu was entitled only to Matrix B-1, Level III benefits. He disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Larrieu's claim should be paid. On September 20, 2016, an Order was issued to show cause and the matter was referred to the Special Master for further proceedings. See PTO No. 9476 (Sept. 20, 2016).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special

Master. The Trust submitted a reply on January 5, 2017. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether Mr. Larrieu has met his burden of proving that there is a reasonable medical basis for finding that he did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for this finding, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for this finding, we must enter an

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Larrieu argues that the Trust merely accepted the conclusions of the auditing cardiologist and ignored the evidence that claimant presented. He contends that a reduction factor such as mitral annular calcification must be diagnosed between the commencement of Diet Drug use and the end of the Screening Period in order to reduce his claim from Matrix A to Matrix B. He further asserts that Dr. Penkala is the only one of five cardiologists who reviewed the December 9, 2002 echocardiogram and found the presence of mitral annular calcification. Finally, according to Mr. Larrieu, calcification of the posterior leaflet of the mitral valve is present, and it is not the same as mitral annular calcification.

The Trust counters that the Settlement Agreement requires denial of the claim because the auditing cardiologist determined that there was no reasonable medical basis for the Green Form representations at issue. The Trust also points out that we previously have rejected the argument that the Trust may not rely on echocardiograms conducted after the Screening Period to find the presence of a reduction factor such as mitral annular calcification. Finally, the Trust reasserts that Mr.

Larrieu has not established a reasonable medical basis for his claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for finding that Mr. Larrieu did not have mitral annular calcification. Dr. Vigilante stated, in pertinent part:

I reviewed the tape of the Claimant's Eligibility echocardiogram. This study was dated December 9, 2002. . . . This was a below quality, grainy, and short study. It was also an incomplete study as there was no adequate apical two chamber view. However, this study was diagnostic in evaluation of the issues in the parasternal long axis, parasternal short axis, and apical four chamber views. The Nyquist limit was set approximately at 54 cm per second in the apical four chamber view. However, there was excessive color gain with color artifact noted outside the cardiac chambers. The mitral leaflets were minimally thickened but opened and closed normally. There was no evidence of mitral valve prolapse or ruptured cords. In addition, there was no definitive evidence of mitral annular calcification in the parasternal long axis, parasternal short axis, or apical four chamber views. There was no significant increase in echo density of the mitral annulus in any of these views. Therefore, mitral annular calcification was not present on this study. . . .

. . . .

I also reviewed the CD of the April 14, 2012 echocardiogram. . . . I reviewed all 36 images/loops. This was a fair quality study with the usual views

obtained. Evaluation of the mitral valve demonstrated thickening of the leaflets. There was clear evidence of mitral annular calcification. There was significant thickening of the mitral annulus as well as increased refractoriness of the echoes classic for mitral annular calcification. The mitral annular calcification was most impressively seen in the anteroseptal annulus on loops 25 and 26. The calcification was most impressively seen in the posterolateral annulus on loops 1 and 9. . . .

I reviewed the DVD of the Claimant's transesophageal echocardiogram dated March 5, 2015. This was an excellent study with all 60 images/loops evaluated. Evaluation of the mitral valve demonstrated thickened mitral leaflets with some restriction of posterior leaflet excursion. There was no mitral valve prolapse. There was obvious mitral annular calcification most impressively involving the anteroseptal area of the annulus in loop 15 and the posterolateral annulus in loop 16. This calcification is demonstrated with significantly increased thickening of the annulus and marked increased refractoriness of the echoes consistent with calcification. This correlates with the findings of the Claimant's cardiac surgeon at the time of mitral valve replacement. . . .

. . . .

In response to Question 2, there is a reasonable medical basis for finding that Claimant had mitral annular calcification. That is, the echocardiograms of April 14, 2012 and March 5, 2015 show evidence of classic mitral annular calcification. An echocardiographer could not reasonably conclude that mitral annular calcification was not present on these studies even taking into account inter-reader

variability. Of course, this mitral annular calcification was definitively diagnosed at the time of mitral valve surgery as documented in the operative report.

After reviewing the entire show cause record, we find that Mr. Larrieu's arguments are without merit. As previously noted, the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). We disagree with Mr. Larrieu that there is a reasonable medical basis for finding that he does not have mitral annular calcification.

As an initial matter, Mr. Larrieu maintains that the Trust must establish the presence of mitral annular calcification prior to the end of the Screening Period. We have rejected this argument, ruling that "[t]o avoid receiving reduced Matrix Benefits, claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim." See Mem. in Supp. of PTO No. 8822 at 9 (Feb. 22, 2012), aff'd, In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine Prods. Liab. Litig., 525 F. App'x 140 (3d Cir. 2013); see also Mem. in Supp. of PTO No. 8743 at 2-7 (Dec. 27, 2011).

In addition, Dr. Penkala and Dr. Vigilante each

reviewed claimant's April 14, 2012 and March 5, 2015 echocardiograms and concluded that they demonstrated mitral annular calcification. Specifically, Dr. Penkala noted that "significant [mitral annular calcification] was present." She explained that on the April 14, 2012 echocardiogram "the presence of [mitral annular calcification] was most evident in loops 1, 9, 25 and 26" and that on the March 5, 2015 echocardiogram mitral annular calcification was seen in loops 12, 15, 16, and 41. Dr. Vigilante also found with respect to the April 14, 2012 echocardiogram, that "[t]here was clear evidence of mitral annular calcification" that "was most impressively seen" in loops 1, 9, 25, and 26. With respect to the March 5, 2015 echocardiogram, Dr. Vigilante determined that "[t]here was obvious mitral annular calcification most impressively" seen in loops 15 and 16.

Mr. Larrieu's arguments regarding the presence of mitral annular calcification are also undermined by the contemporaneous operative report prepared following Mr. Larrieu's valve replacement surgery. The surgeon, Lisardo Garcia Covarrubias, M.D., noted "[i]t was immediately evident that the mitral valve had severe calcification of the posterior leaflet, as well as the annulus, mainly at the level of P1 and P2." Dr. Covarrubias further stated, "[a]s I mentioned before, the valve was very calcified, including the annulus."

Claimant's position to the contrary is without merit.

We reject Mr. Larrieu's argument that his claim should not be reduced because the level of his mitral annular calcification, if any, is "relatively minute or insignificant." The Settlement Agreement specifically provides that a claimant will receive reduced Matrix Benefits for a mitral valve claim if he or she is diagnosed by echocardiogram with mitral annular calcification. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). The Settlement Agreement provides that the presence of mitral annular calcification, regardless of level, requires the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of mitral annular calcification, regardless of the amount, places the claim on Matrix B-1. Compare Settlement Agreement § IV.B.2.d.(2)(c)ii)d) with Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilatation > 5.0 cm").

Finally, Mr. Larrieu's suggestion that any mitral annular calcification is the result of his age is misplaced. Causation is not at issue in resolving Mr. Larrieu's claim for Matrix Benefits. Rather, claimant is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover

Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred....

Mem. in Supp. of PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

[I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true. In applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the conditions at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced from Matrix A to Matrix B-1 if any amount of mitral annular calcification is present. We must apply the Settlement Agreement as written. Accordingly, claimant's argument that any mitral annular calcification was not the cause of his mitral valve replacement surgery is irrelevant.

For the reasons stated above, we conclude that Mr. Larrieu has not met his burden of proving that there is a reasonable medical basis for finding that he did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Mr. Larrieu's claim for Matrix A-1 Benefits.